

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

ELIZABETH ANGELL and
BRETT ANGELL,

Jacksonville, Florida

Plaintiffs,

Case No.: 3:18-cv-282-J-34JBT

v.

Date: June 20, 2019

ALLERGAN SALES, LLC,

Time: 10:33 a.m. - 11:52 a.m.

Defendants.

Courtroom: 10B

ASHLEY HICKS,

Plaintiff,

Case No.: 3:18-cv-283-J-34JBT

v.

ALLERGAN SALES, LLC,

Defendants.

MOTION HEARING

BEFORE THE HONORABLE MARCIA MORALES HOWARD
UNITED STATES DISTRICT JUDGE

OFFICIAL COURT REPORTER:

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(Proceedings reported by stenography; transcript
produced by computer.)

A P P E A R A N C E S

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P R O C E E D I N G S

June 20, 2019

10:33 a.m.

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COURT SECURITY OFFICER: All rise.

The United States District Court, in and for the Middle District of Florida, is now in session. The Honorable Marcia Morales Howard presiding.

Please be seated.

THE COURT: All right. We are here on two cases, Case No. 3:18-cv-282-J-34JBT, styled *Elizabeth Michelle Angell* -- is that how you pronounce it? Is it Angle or Angel?

How does she pronounce it?

MR. SHAKIB: Angell, Your Honor.

THE COURT: *Angell*, okay.

Angell and Brett Angell versus Allergan Sales, LLC. And Case No. 3:18-cv-283-J-34JBT, *Ashley J. Hicks versus Allergan Sales, LLC.*

Counsel, beginning with the plaintiff, if you could please make your appearances for the record.

MR. GOWDY: Bryan Gowdy of Creed & Gowdy, on behalf of plaintiff.

MR. SHAKIB: Christopher Shakib of Terrell Hogan for the plaintiff.

THE COURT: And for Allergan Sales, LLC?

MR. MCGUIRL: Good morning, Your Honor. Robert J.

1 McGuirl for Allergan.

2 MS. VOSS: Good morning, Your Honor. Jennifer Voss
3 from Shook, Hardy & Bacon.

4 THE COURT: All right. Mr. McGuirl, it is your
5 motion, and so let me hear from you.

6 And I guess maybe you could start with addressing --
7 you-all lead off with a preemption argument. And the plaintiff
8 has suggested that that's not the right way for the Court to
9 start, that I first need to start with whether or not the
10 claims actually state a claim.

11 Do you want to start by addressing that?

12 MR. MCGUIRL: Sure.

13 Do you want me at the podium, Judge, or here?

14 THE COURT: Yes, yes.

15 And just -- so for purposes of the record, we are
16 here on the motions to dismiss that have been filed.

17 The -- both Ms. Angell and Ms. Hicks' claims are
18 before the Court on their second amended complaints. Those are
19 Document No. 45 in each case.

20 Allergan has filed motions to dismiss the second
21 amended complaints. Those are documents No. 46 in each case.

22 The plaintiffs have responded in Document No. 51 in
23 each case.

24 And with leave of Court, defendant filed replies that
25 are document No. 54.

1 So that is the record that is before the Court.

2 MR. MCGUIRL: And, Judge, thank you for allowing me
3 to appear pro hac vice.

4 And the second thing, if the rain is an omen, I'm not
5 sure what it means, but, you know, we'll go from there.

6 THE COURT: We've been having a lot of rain this
7 week. So...

8 MR. MCGUIRL: Throughout -- you can look at the U.S.
9 Supreme Court in *Riegel*, and in any of the cases that come from
10 *Riegel*, there's no doubt that a preemption analysis is a
11 two-step analysis, whether there are requirements -- and we
12 know with the PMA, it's clear there are requirements. And then
13 whether what's being proffered by the plaintiff in the case
14 includes requirements that are different from or in addition to
15 those imposed by the FDA.

16 So that's definitely the approach you need to take on
17 preemption, there is no doubt.

18 Because -- what the plaintiffs are arguing, the
19 linchpin of their argument is in this lab testing that was done
20 by Allergan for the Food and Drug Administration. And to
21 impose requirements in addition to those or different from
22 those will preempt that knowledge, and that causes the rest of
23 the state law claims, which we can then analyze, to fall.

24 So I do suggest preemption first is the analysis.

25 THE COURT: Well, the Eleventh Circuit, in *Mink*,

1 says: Because preemption is a principle derived from the
2 supremacy clause, we must first analyze whether each claim can
3 stand under state law and only then decide the preemption
4 question when necessary.

5 So don't I have to do what the Eleventh Circuit tells
6 me to do?

7 MR. MCGUIRL: It's a nice quote for plaintiffs from
8 *Mink*, no doubt. But if you read the rest of what goes on in
9 *Mink*, it's really talking about the state law claims having to
10 do with the representations by the physician to the patient,
11 which are separate claims, as *Mink* goes on to say, from the
12 preemption claims.

13 You can -- in the end -- at the end of the day, Your
14 Honor, it's not going to make a big difference.

15 THE COURT: And why is that?

16 MR. MCGUIRL: Because the key to what the plaintiffs
17 are arguing are that the lab tests imposed by the FDA required
18 Allergan to do more than what the FDA required them to do.

19 If you don't have that -- and I'll get to that in the
20 argument -- you can't have their conspiracy claims because you
21 don't have the agreement to do anything with knowledge of what
22 you're doing. You don't have an overt act in furtherance of
23 it. You don't have knowledge for aiding and abetting.

24 You need -- at the core of this is -- for plaintiffs'
25 argument, you need to have Allergan doing more than the FDA

1 required.

2 You need Allergan to -- in addition to supplying the
3 data from the tests, analyzing it. And that's a requirement
4 above and beyond what the FDA had asked for.

5 THE COURT: I don't think the plaintiffs are relying
6 on the fact that the FDA requires Allergan to do the testing.

7 MR. MCGUIRL: They're not.

8 THE COURT: The plaintiffs are relying on the mere
9 fact that Allergan does the testing. So...

10 MR. MCGUIRL: Let's talk -- can we talk about what
11 the testing is? Because that's kind of the key here.

12 Because what the FDA is requiring for testing is not
13 what the plaintiffs are basing their claims on.

14 Let's just go into it for a second, and I think it
15 will start to get a little bit clearer, Your Honor, if you bear
16 with me.

17 THE COURT: What does -- well --

18 MR. MCGUIRL: Here's what the FDA asked for.

19 THE COURT: Whoa, whoa, whoa.

20 MR. MCGUIRL: I'm sorry, Judge. I'm sorry.

21 THE COURT: First of all, there aren't any
22 allegations about what the FDA requires in testing in the
23 plaintiffs' complaint.

24 You're relying on the PMA, postmarketing analysis
25 document?

1 MR. MCGUIRL: That's correct. That's correct.

2 THE COURT: And I think it's your position that
3 because that's a public record, the Court can take judicial
4 notice of that specific document, of those requirements?

5 MR. MCGUIRL: That's correct, Your Honor.

6 And pretty much all the preemption case law stands
7 for that, otherwise you couldn't have preemption on a motion to
8 dismiss.

9 THE COURT: And so what is it that -- plaintiffs
10 allege that Allergan does testing to determine -- well,
11 plaintiffs don't allege what it's seeking to determine.

12 Plaintiffs allege that Allergan does postwarranty
13 claim testing, and that that testing shows that none of or
14 nearly none of the breast implants that were returned by the
15 Clayman practice had the deficiency that was identified.

16 Right?

17 MR. MCGUIRL: That's not what's required by the FDA.
18 Nobody's ever done that testing and there's no duty to do the
19 testing.

20 Can we just back it up, Judge, please?

21 THE COURT: Sure.

22 MR. MCGUIRL: Let's back it up.

23 The FDA regulates device manufacturers.

24 Uncontroverted. We all know that.

25 Nowhere is that regulation and the scrutiny and the

1 intensity of that regulation greater than in a premarket
2 approved product.

3 Okay? I think we can all agree on that. Not -- it's
4 not controverted.

5 You know, the 1200 hours of review, the submission of
6 samples, the directions for use. That risk benefit analysis,
7 that safety and effective analysis, that's done by the FDA.
8 It's not done by Allergan.

9 Allergan basically hands over data, hands over
10 information, literature, whatever the FDA wants or needs for
11 that premarket approval. And that's in the process. It's in
12 the chapter.

13 And then the FDA, as they say in *Riegel*, it doesn't
14 do something substantially similar to safety and effective
15 analysis, it does safety and effective analysis.

16 The FDA makes the decision on whether the device is
17 safe and effective, balancing, you know, risks and benefits.

18 So what they're focusing on is the safety and
19 effectiveness of the device.

20 So when they do that, they're going to Allergan:
21 Give me this. Give me that. Give me this. Give me more of
22 that. I want to see this. I want to see that.

23 That's basically what goes on in the PMA process.

24 And Allergan can put in their two cents, but at the
25 end of the day, it's the FDA running the show here. And you

1 either give them what they ask for or you don't, and then the
2 FDA makes the decision.

3 Once they make that decision, which they did here,
4 they can then impose, as they did here, postapproval
5 requirements.

6 And one of the things they did -- and you'll see it's
7 No. 2 in the PMA, you know, to grant the PMA, they continue to
8 monitor.

9 And why are they doing it? For safety and
10 effectiveness. That's the point of the whole chapter. That's
11 the point of postmarket approval.

12 And they say: We want you to do -- to retrieve
13 explanted devices.

14 Now, let's stop for a minute.

15 There's no federal requirement to retrieve -- for any
16 medical device manufacturer to retrieve explanted devices.
17 There's no state law that requires any manufacturer to retrieve
18 explanted medical devices. It doesn't exist.

19 But the FDA, if they put in that PMA as part of this
20 approval you're going to retrieve, as best you can, explanted
21 devices.

22 What's Allergan say on that? Yes, sir.

23 You do it. That's it. There's not any discretion
24 there.

25 And it also says: By the way, we want you -- we're

1 doing this for safety and effectiveness. We want you to take
2 that device and we want to see -- we want you to do a visual
3 examination. We want you to do histological examination. We
4 want you to give us a failure cause, if it is a failure.

5 And here's what we want you to do with that data --
6 you have to pay for the lab work, by the way, and you have to
7 do this testing. You have to give us the data.

8 Nobody asked you to analyze it. You give us the
9 data. We're running the show here, not you, Allergan.

10 Why are we doing this? Because we want to see, over
11 time, through this study, what's happening with these implants,
12 what the failure rates are, et cetera. So you give us the
13 data. We will do the analysis.

14 THE COURT: Okay. But, regardless, plaintiffs allege
15 that over this eight-year period of time, Allergan receives
16 over 5,000 explanted implants.

17 MR. MCGUIRL: Right.

18 THE COURT: That show no failure, from Dr. Clayman's
19 practice. And Allergan pays all of these warranty claims with
20 a blind eye.

21 MR. MCGUIRL: Can I -- I hear you. I'm with you.
22 I'm not -- I'm not disagreeing, obviously, Judge.

23 But let me continue on this, because the requirements
24 from the FDA -- remember what the FDA is doing. They don't --
25 you know what, there's no requirement to do more.

1 THE COURT: I understand that. I understand that the
2 FDA isn't requiring that.

3 But plaintiff -- plaintiffs' claims -- they aren't
4 basing it on the FDA's requirements. You-all are bringing up
5 the FDA requirements as a defense.

6 But plaintiffs' claim is that because Allergan is
7 receiving, time and time and time again, almost every time,
8 warranty claims from Dr. Clayman that say on the warranty claim
9 that it is a ruptured, deflated, or leaking implant, and when
10 they examine it, it isn't, that based on that history, at some
11 point Allergan obtained actual knowledge that Dr. Clayman was
12 defrauding his patients, was intentionally lying to his
13 patients about the need for another surgical procedure so he
14 could make the money off the warranty claim.

15 That's their claim.

16 So address why --

17 MR. MCGUIRL: There's no -- yeah, I'm sorry.

18 THE COURT: Why isn't it -- why isn't Allergan seeing
19 that every single warranty claim that Mr. -- or Dr. Clayman or
20 his practice submits is for a nondefective implant, yet they're
21 still paying them?

22 MR. MCGUIRL: We're not saying, in hindsight, in
23 retrospective, that you couldn't do this in hindsight.

24 What we're saying is that the data we produced from
25 these lab tests went to the FDA, and only the FDA, and was

1 produced for that purpose.

2 And there was no duty, not even an incentive, no
3 interest in trying to get into the supervision of physicians in
4 Florida.

5 We're not in the practice of medicine. We're not in
6 the medical supervisory position. We're not some super Florida
7 Board of Medical Examiners. Neither is the FDA.

8 We don't do those lab tests for the purpose of
9 examining physician conduct.

10 Nobody is told -- the FDA doesn't, we don't -- we
11 have no interest in taking those lab tests and trying to
12 correlate them with some claims in some other department, and
13 then make, on the basis of no knowledge whatsoever -- we have
14 no medical knowledge that goes to what a physician is doing in
15 his OR, and we're then going to make the judgment -- no
16 complaint from the patient, no complaint from the physician --
17 we're then going to, from 3,000 miles away, somehow think that
18 we know what is going on there.

19 We can surmise -- no medical records, no OR, no
20 anything, we're going to then surmise that we know what's
21 happening back in that conference room. We know what's
22 happening in that OR.

23 There's no way we could know that. There's no way we
24 could figure out what it means.

25 But more importantly, there's no duty. There's no

1 reason to put together -- over in the section that's sending
2 the stuff to the FDA, there's no reason to put that together in
3 the warranty claims.

4 The warranty claims are just that. They do not
5 require a lab test to back them up. These are separate things.
6 They are apples and oranges.

7 The plaintiffs' theory is: No, there's a duty.
8 There's a duty to do more than just give this data to the FDA.
9 You have to supervise the patient's physicians.

10 You have to take this data, which is only for the FDA
11 for failure rates, you have to take it and you have to track it
12 by physicians.

13 The FDA didn't ask for that. There's no duty to do
14 that. I'm not saying you couldn't possibly do it, Judge.
15 There's no duty. There's no incentive to do that. And there's
16 nothing you can do with it, anyway, even if you did.

17 These patients all have a Florida Board of Medical
18 Examiners. They have civil complaints. If there's something
19 awry going on, the patient would know, the physician would
20 know. There's no way that Allergan can know from 3,000 miles
21 away.

22 THE COURT: What if, hypothetically, Allergan and the
23 Claymans agreed that as long as he did \$5 million worth of
24 business every year they would pay all of his warranty claims?

25 MR. MCGUIRL: Now, think about that discussion.

1 First of all, that's not alleged. None of the
2 details of any agreement beforehand are alleged.

3 But think about that discussion. Here's Dr. Clayman.
4 They're going to have a meeting. So here's what I want to do.
5 I want to commit malpractice on thousands of people.

6 THE COURT: I understand that your argument is that's
7 not logical. But hypothetically, if they said that, wouldn't
8 that state a cause of action?

9 MR. MCGUIRL: You mean if they said: This is what
10 we're going to do?

11 THE COURT: Uh-huh.

12 MR. MCGUIRL: But that's not pled, Judge. It's not
13 pled. You know why it's not pled? Because it didn't happen.
14 They're not even claiming it happened. They're not claiming
15 that happened.

16 They are -- just like you can any week just turn on
17 Channel 7 or ABC or something, and every week there'll be a
18 conspiracy of -- you know, you can -- you could think of
19 conspiracies in hindsight of everything.

20 Every week, somebody on one of these shows is saving
21 the world from whatever, and you can tie in whatever you want.
22 In hindsight, you could construct these theories.

23 They're not alleging that meeting would occur ahead
24 of time. They didn't occur [verbatim] it happened.

25 THE COURT: Let's talk for a moment about preemption,

1 because I want to hear from Mr. Gowdy.

2 Why -- so the plaintiff is alleging a fraud claim and
3 a breach of fiduciary duty.

4 And the fraud claim is based upon what they contend
5 is the intentional misrepresentation by Dr. Clayman -- Drs.
6 Clayman, the two -- to the patients that their implants had
7 deflated or ruptured or were leaking, and therefore they could
8 have a second surgery under warranty for free, and that
9 prevented these patients from going to another doctor and
10 perhaps getting better treatment or un -- or not undergoing an
11 unnecessary surgery from Dr. Clayman.

12 That's the fraud that they claim; right?

13 MR. MCGUIRL: Well, you're giving more specificity, I
14 think, than they did. But, yes, Your Honor.

15 THE COURT: No. All of that is --

16 MR. MCGUIRL: Okay.

17 THE COURT: All of that is --

18 MR. MCGUIRL: All right.

19 THE COURT: That, to me, is a traditional state law
20 claim that absolutely predates any of the federal regulations
21 that we're talking about.

22 MR. MCGUIRL: Against the Claymans.

23 THE COURT: Akin to the misrepresentation claim in
24 *Mink* that was --

25 MR. MCGUIRL: It's a straight fraud claim against the

1 Claymans, no doubt, but that's not what's being pled against
2 us.

3 THE COURT: Well, what's being pled against you is
4 that you aided and abetted in that straight fraud claim
5 against --

6 MR. MCGUIRL: Yes. Which is not a straight fraud
7 claim. What's being -- fraud is not -- well, it's not.
8 There's a difference in aiding and abetting and conspiracy.

9 When you get to aiding and abetting, there has to be
10 actual knowledge, not constructive knowledge. There has to be
11 actual knowledge on our part that we know what is going on.

12 We know that he's going to lie to them and he's going
13 to lie to us.

14 THE COURT: But if there is actual knowledge, then it
15 wouldn't be preemptive; right?

16 MR. MCGUIRL: It would be preemptive, because you
17 know how we got the actual knowledge?

18 THE COURT: Well, that's --

19 MR. MCGUIRL: Under their -- what they plead -- they
20 plead we got the actual knowledge by making us do more than the
21 FDA required us to do under the PMA. That's how they plead we
22 got the actual knowledge.

23 THE COURT: Let's say, hypothetically, you have
24 actual knowledge. Let's say, hypothetically, that the
25 complaint alleged that Allergan actually knew.

1 That wouldn't be preemptive; right?

2 MR. MCGUIRL: The only way their -- you mean without
3 regard to the lab tests?

4 THE COURT: Pretend the complaint says there was
5 somebody at Allergan who knew what Dr. Clayman was doing. If
6 they're not relying on the lab tests, that would not be
7 preemptive.

8 MR. MCGUIRL: If they're not relying on the lab
9 tests, then they would just have to show actual knowledge.
10 They'd have to show someone at Allergan conspiring to do this
11 for whatever the reason.

12 THE COURT: And if they show the actual knowledge,
13 the claim would not be preemptive, because it would just be a
14 traditional state law claim.

15 MR. MCGUIRL: Independent -- if the knowledge doesn't
16 come from the lab test, yes.

17 THE COURT: Okay. So if -- well, if the Court
18 concludes that they have pled sufficient factual matter to
19 raise a plausible claim of actual knowledge, then the claim
20 would not be preempted.

21 MR. MCGUIRL: So we're putting aside the lab test as
22 the source of knowledge?

23 THE COURT: No, no. I'm saying even -- because
24 your -- it's only your contention that the lab tests are done
25 simply based on the FDA requirements. That is --

1 MR. MCGUIRL: That's in the PMA.

2 THE COURT: Well, the PMA does require them to do the
3 lab testing.

4 MR. MCGUIRL: And it says what their visual
5 examination and for explantations and failure to send it back
6 the data. No analysis, just the data. That's what it says.

7 THE COURT: Right. But that isn't --

8 MR. MCGUIRL: That's what they did.

9 Plaintiff is saying they should have done more.

10 THE COURT: Plaintiffs, arguably -- arguably --

11 MR. MCGUIRL: Well, that's what's preempted. That's
12 what's preempted. You should have done more.

13 And can we talk about that?

14 Should have done more why? We don't regulate
15 physicians. The FDA doesn't regulate physicians.

16 A, we're not required to do more; and, B, why would
17 we?

18 What are we going to do with it?

19 We can't do anything with it.

20 THE COURT: Why can't you?

21 MR. MCGUIRL: What are we going to do, call up the
22 Florida Board of Medical Examiners and say: Hey, here's what
23 we have, when the patients don't want to do it?

24 We're going to intrude and tell the patients and the
25 doctors: You're all frauds because we have a suspicion?

1 THE COURT: How does their -- their claim is --

2 MR. MCGUIRL: You're going to tell the doctor and the
3 patient they're liars?

4 THE COURT: Whoa. You need to let me finish my
5 question.

6 MR. MCGUIRL: I'm sorry, Judge. Sorry.

7 I get carried away.

8 THE COURT: I can tell.

9 To avoid preemption, a plaintiff must carefully plead
10 a claim that implicates the safety and effectiveness of a
11 federal-related medical device; right?

12 MR. MCGUIRL: Yeah. Or any other requirement under
13 that chapter, yes.

14 THE COURT: But their misrepresentation claim doesn't
15 relate in any way to the safety or effectiveness of the device.

16 MR. MCGUIRL: They don't have a misrepresentation
17 claim, not against us.

18 THE COURT: Their fraud claim.

19 MR. MCGUIRL: Not against us. They don't have a
20 fraud claim or misrepresentation against us.

21 THE COURT: Their aiding and abetting in the fraud,
22 and their aiding and abetting in the breach of fiduciary duty
23 don't have anything to do with the safety or effectiveness of
24 the device; right?

25 MR. MCGUIRL: Yes, it does. Because the way they're

1 saying that you have to take what's the safety and
2 effectiveness, the data you give to the FDA, and you have to do
3 something in addition to and different from what you're doing
4 that for, you have to do that -- you know why? You know where
5 the duty comes from, because we just say so. We just say so.

6 There's no duty. There's no obligation to do it.
7 And it's something different in addition to what they're
8 required to do by the FDA. That's why it's preempted.

9 They're saying: You have to do more. You have to do
10 more. And you have to do more so that you can come to this
11 knowledge so that we can make this claim.

12 But there's no state law duty to make that, you know,
13 retrieval study or to do the lab -- there's no federal
14 requirement to do that. There's no parallel claim. There's
15 nothing.

16 They're just making up this idea -- now, they don't
17 plead there was any meeting, you know, as Your Honor has
18 hypothesized, where people got together and said: Let's agree,
19 you're going to do malpractice. You're going to lie to us.
20 You're going to lie to them. And everybody is going to -- why
21 are we doing this again?

22 I mean, why do you even need this? If you're going
23 to be lying to us, why don't you just submit the claims and pay
24 them? Which is, by the way, what happened.

25 What do we need the lab tests for?

1 Why are we involved in this?

2 Why would you tell us you're going to defraud us?

3 It makes no sense.

4 THE COURT: In your motion papers, you argue that
5 Allergan gets the warranty claim and pays the warranty claim
6 based solely on the doctor's sworn statement.

7 MR. MCGUIRL: Yeah.

8 THE COURT: And that it isn't -- it isn't -- pardon
9 me, it isn't until after the surgery that you do the warranty
10 implant, but that isn't pled anywhere in the complaint.

11 Aren't you relying on facts that are outside the
12 complaint?

13 MR. MCGUIRL: I think that goes into more detail on
14 the way the warranty program works.

15 But I think -- I'm conceding, it goes into more
16 detail. In fact, that is the way the warranty works, but it's
17 not before Your Honor.

18 THE COURT: Right. Okay.

19 MR. MCGUIRL: I'm just telling you, by way of
20 background, you cannot rely on it, but just so you know, Judge,
21 when they get the diagnosis by a physician sworn to and signed
22 by the patient that there's been a failure --

23 THE COURT: Well, if I can't rely on it, there's no
24 reason --

25 MR. MCGUIRL: I'm just telling you -- just so you

1 understand.

2 THE COURT: I get it.

3 MR. MCGUIRL: They send it so there doesn't have to
4 be two surgeries. That's why they do that.

5 But, you know, there's no requirement in that
6 warranty that we have to do a lab test first. There's nothing.

7 The lab test is a totally -- nowhere in there does
8 the warranty say: Subject to a lab test.

9 And most of modern medicine is built on one physician
10 relying upon another physician.

11 I mean, that's what it's about.

12 You have a reasonable expectation that physicians,
13 with their patients, aren't lying to you on diagnoses.

14 THE COURT: All right. Let me talk to Mr. Gowdy.

15 MR. MCGUIRL: Thank you, Judge. Sorry to get going
16 there.

17 THE COURT: It's quite all right.

18 All right. Mr. Gowdy, just so that you and I are on
19 the same page.

20 MR. GOWDY: Yes, Your Honor.

21 THE COURT: You agree that under Florida law, in
22 order to state a claim for either the aiding and abetting of a
23 fraud or the aiding and abetting of a breach of fiduciary duty,
24 you have to present sufficient allegations to state a plausible
25 claim that Allergan had actual knowledge that Dr. Clayman was

1 lying to his patients about the implant in order to get the
2 warranty money; right?

3 MR. GOWDY: Yes.

4 THE COURT: So they're --

5 MR. GOWDY: And that's what we're traveling under is
6 actual knowledge, not should have known.

7 THE COURT: Okay. So tell me -- in the complaint,
8 you allege that Allergan knew the warranty claim showed
9 Dr. Clayman told the patients their implants were ruptured,
10 deflated, or leaking.

11 And, actually, on that, let me ask you this. I don't
12 think -- in Ms. Hicks' complaint, I don't think she even
13 alleges that Dr. Clayman told her that. She says that she
14 filled out a warranty claim that said it.

15 Ms. Angell does say that he told her her implant was
16 leaking. But Ms. Hicks, I think, simply alleges that she was
17 unhappy with the size and the symmetry of the implant.

18 MR. GOWDY: Let me see about -- well, the Claymans --
19 I guess, on November 14, 2004 -- and this was Dr. Clayman,
20 Junior -- had Ms. Hicks sign a form stating she had a right
21 implant deflation.

22 So I'm not sure if there was an oral communication,
23 Your Honor, that's alleged in the complaint, but there
24 certainly was a written communication from Dr. Clayman to that
25 effect.

1 THE COURT: But, I mean, doesn't she -- what she says
2 is that she went back and reported that her left breast was
3 higher than the right, that other parts were not properly
4 aligned, and that she was experiencing firmness, similar to
5 capsular contracture.

6 And then she says that -- or he documents in the
7 records that she wasn't sure if she wants to add a little or
8 remove a little.

9 MR. GOWDY: Right.

10 THE COURT: And that Dr. Clayman gave her a surgical
11 estimate for the procedure with no charge.

12 MR. GOWDY: Right.

13 THE COURT: And then when she comes back, he has --
14 they have her sign the --

15 MR. GOWDY: Informed consent. Paragraph 45.

16 THE COURT: Right.

17 MR. GOWDY: The informed consent form stated she had
18 a, quote, "right implant deflation," for which she needed to
19 have both of her implants removed and replaced.

20 And then the Claymans -- I think it was Clayman,
21 Junior, specifically -- had her sign an Allergan warranty claim
22 form that stated she had deflation at her right breast implant.

23 So I think that's -- I'm not sure -- I guess --
24 anyway, we're both reading the same complaint. That's where
25 there was --

1 THE COURT: That's the basis of that, okay.

2 MR. GOWDY: And he then submitted a warranty claim.

3 And I guess -- I want to answer the Court's
4 questions, but I wanted to answer your questions from before,
5 too, but I'll wait.

6 THE COURT: Sure.

7 Well, I guess -- I guess the question there is why
8 isn't that equally consistent with Dr. Clayman and his patient
9 working together to get the surgery for free for her as opposed
10 to Dr. Clayman defrauding her into believing that the problem
11 was a leaking implant?

12 MR. GOWDY: Well, I guess I have a couple responses.

13 One is we have to show it's plausible. And if they
14 want to come forward with their -- what I heard a lot of a few
15 minutes ago were jury arguments, not about the plausibility of
16 our claims.

17 But I think the reason it's not is when you step back
18 and look -- it's not equally consistent is when you step back
19 and you look at the whole picture, that this was going on for
20 years where the Claymans were doing this with every patient,
21 more than once a day, and they were submitting false claims to
22 Allergan that Allergan paid.

23 And I want to, I guess, segue into nothing in the
24 FDCA or any federal regulation or the PMA compelled Allergan to
25 pay these false warranty claims. In fact, as we allege in the

1 complaint, they routinely denied warranty claims from other
2 physicians.

3 THE COURT: Actually, let's talk about that
4 allegation, because I -- I'm not sure there is an allegation
5 anywhere in the complaint about Allergan -- how Allergan treats
6 other warranty claims.

7 The --

8 MR. GOWDY: It's paragraph 34 of the Hicks'
9 complaint.

10 THE COURT: Right. So paragraph 34 says: Other
11 plastic surgeons report that in response to their saline breast
12 implant warranty claims, Allergan demanded further proof that
13 the claimed ruptures, deflation, or leaks were not the results
14 of actions by patients or surgeons, even though these other
15 plastic surgeons made fewer than five saline breast implant --

16 MR. GOWDY: Right. So I stand corrected. It doesn't
17 say specifically there was a denial, but the point being that
18 they treated other surgeons who didn't provide the same volume
19 of business differently.

20 THE COURT: Well, but this, as I read it, is
21 saying -- nowhere in this complaint does it -- is there any
22 allegation that Allergan ever turned -- denied any warranty
23 claim.

24 There's no comparison of how many warranty claims
25 other doctors submitted and whether those were paid or not.

1 This allegation talks about Allergan demanding proof
2 that what went wrong was not the fault of the patient or the
3 surgeon.

4 MR. GOWDY: Right. And I think Your Honor is raising
5 excellent points that once we get beyond the pleading stage
6 that Allergan may try to bring forward.

7 We're not required to prove our whole case here.
8 We're required to have a plausible basis that there was
9 knowledge on behalf of Allergan.

10 THE COURT: Well -- and actual knowledge. And that's
11 kind of what I'm struggling with is -- well, it is what we're
12 all struggling with on this, is you have that Allergan paid all
13 of -- arguably, all of the warranty claims. That when they
14 examined the implants, they were found to be nondefective.

15 But where -- where in the complaint do I have facts
16 plausibly alleging that Allergan makes that connection, that
17 Allergan goes back and matches up warranty claims with a doctor
18 and draws the inference that they're making the false warranty
19 claims?

20 MR. GOWDY: Yeah, and I would say that we don't -- we
21 don't have to connect the dots to that extent, or nor do what
22 my opponent suggested that we have to show some type of actual
23 meeting or some, you know, oral handshake or something like
24 that.

25 THE COURT: No, you don't.

1 MR. GOWDY: Right, I'm sorry.

2 But I would encourage the case -- the Court to read
3 the *Halberstam* case from the D.C. Circuit that was authored by
4 Judge Wald and Judge Bork and Judge Scalia -- at the time,
5 Judge Scalia. It goes through thoroughly and talks about both
6 aiding and abetting liability and conspiracy liability.

7 And even though it's not a Florida case, it is
8 recognized as the seminal explanation on the common law of
9 these two torts, aiding and abetting, and conspiracy.

10 And it makes it very clear that -- and as Your Honor,
11 I'm sure, is aware from having done many criminal conspiracy
12 trials, that the way you generally show an implicit agreement
13 or some type of accomplice liability is by the circumstances
14 surrounding the transactions.

15 THE COURT: Sure.

16 MR. GOWDY: And we -- you know, this is a 20 -- I
17 don't know how many pages -- almost a 30-page complaint, and
18 I'm sure holes can be poked into it, but we're -- I think given
19 the volume of warranty claims and the fact that they inspected
20 these devices -- it doesn't matter why they did it. It doesn't
21 matter if they did it because of the warranty, which is part of
22 the reason they did it. It doesn't matter if the FDA did it.
23 It doesn't matter if they did it voluntarily.

24 Once they did it and they learned it, that's the --
25 that's the knowledge for that prong of an aiding and abetting

1 claim.

2 THE COURT: All right. So two things I want to
3 address that you've just brought up.

4 First of all, *Halberstam*, you-all rely on it for the
5 proposition that all you have to do is allege facts suggesting
6 a general awareness, and that can be done circumstantially, and
7 that's true. But it has to be a general awareness of the
8 person's role in the tortious conduct, which requires knowledge
9 of the tortious conduct.

10 There has to be actual knowledge of the tortious
11 conduct. And even *Halberstam* says that.

12 MR. GOWDY: Yes. I would agree to that, but it
13 doesn't -- but the specificity is not, I think, perhaps what
14 Your Honor may be suggesting.

15 In the facts of *Halberstam*, recall that the tortious
16 conduct was a murder. And there was no suggestion at all that
17 the civil defendant, Ms. Hamilton, knew about Mr. Welch's
18 murder. But what -- and there was -- she never participated in
19 any of the burglaries.

20 THE COURT: But she knew about the purpose of the
21 burglaries.

22 MR. GOWDY: Well, she -- right, she -- if you read
23 it, there's a lot of -- there's a lot of individual facts, when
24 put together, would give someone reason to know that Ms. -- I
25 think I got the names -- Mr. Welch was engaging in burglaries

1 at night. And therefore that was enough for a finder of
2 fact -- there was a bench trial -- for a finder of fact to find
3 that she knew about the tort, which -- which was really just
4 the burglary, not the murder.

5 THE COURT: Right.

6 MR. GOWDY: And therefore, here, there's enough for
7 them to know -- for Allergan to have known that the Clayman
8 practice was falsely stating that the implants were defective,
9 when, in fact, they were not defective. That they were doing
10 unnecessary surgeries, because the whole basis for these
11 surgeries was that the -- that the implant was defective. And
12 they had that information.

13 How they gathered it is irrelevant. They had it.

14 THE COURT: All right. Let's talk about the bank
15 cases, because --

16 MR. GOWDY: Sure.

17 THE COURT: -- the -- in the bank cases, you have the
18 same circumstance in terms of the bank is seeing -- and in both
19 the *Perlman* and the *Lawrence* case, the bank is -- in those
20 cases, it's not just the sheer number of transactions. The
21 bank actually can see that the money that's being paid in is
22 being used to pay investors out.

23 It's clear that there's -- nothing is coming in from
24 the foreign exchange trading. And the bank is fully aware, not
25 only that the money that's coming in is being used to pay some

1 investors, but that the individual primary tortfeasor is paying
2 himself millions of dollars out of the account, and the bank
3 sees all of that, and yet the Eleventh Circuit says that is not
4 enough under Florida law.

5 Those are red flags. That is suspicious conduct. It
6 is atypical conduct. But they didn't have any duty to inquire
7 about the conduct, and therefore they had no actual knowledge.

8 MR. GOWDY: Right.

9 THE COURT: And I -- how is that any different?

10 MR. GOWDY: Yeah. Because here, Your Honor -- and I
11 want to be clear. Our case isn't about a duty; our case is
12 about what they did, what they actually did.

13 And as we point out, in the *Lawrence* case, the Court
14 said there was no requirement to investigate the perpetrator's
15 transactions. We agree.

16 We agree here Allergan had no duty to investigate
17 Dr. Clayman -- either Dr. Clayman's or the Clayman practice's
18 transactions.

19 What we're saying is that the information they
20 learned in the course of their own investigation that they
21 undertook -- and that ties it back to the *Mink* case -- that
22 they knew that these were lies. They determined they were
23 lies.

24 THE COURT: How did they know they were lies as
25 opposed to Mr. -- the Drs. Clayman aren't very good doctors?

1 How did they know they're lies as opposed to
2 malpractice?

3 MR. GOWDY: Because the claim, the warranty claim,
4 was that the product was defective. And to pay the warranty,
5 you had to show that.

6 And they determined -- Allergan determined -- it was
7 not defective, repeatedly, over 5,000 times.

8 THE COURT: But how did that tell them that
9 Dr. Clayman is lying to his patients as opposed to just being a
10 bad doctor or perhaps helping -- just helping his patients get
11 a new set of implants?

12 MR. GOWDY: Well, again, I have to show it's
13 plausible. And the reason they knew that he was telling the
14 patients that was -- is they got a warranty claim form signed
15 by the patient.

16 Now they want to say: Oh, that means that the
17 patient and Dr. Clayman were in cahoots.

18 Our reading of that is it's pretty clear that
19 Dr. Clayman was telling the patient that the device was
20 defective. That Dr. Clayman was telling Allergan the device
21 was defective. Yet, it was not.

22 And if you had one patient doing that with
23 Dr. Clayman, I think your reading would be plausible. We had
24 over 5,000 patients doing this.

25 So who do you think's at the center of this

1 conspiracy, the patient and Dr. Clayman, or Dr. Clayman and
2 Allergan?

3 I think our allegation is plausible.

4 They knew that Dr. Clayman was telling the patient
5 that because they got the patient to sign the warranty form.
6 And they knew it was a lie.

7 THE COURT: So they get -- they get the warranty
8 form --

9 MR. GOWDY: Right.

10 THE COURT: -- and they determine -- they do their
11 analysis of the implant.

12 MR. GOWDY: And they know it --

13 THE COURT: -- once they --

14 MR. GOWDY: Sorry. Go ahead, Your Honor.

15 THE COURT: No, go ahead. Go ahead, Mr. Gowdy.

16 MR. GOWDY: What they knew was a lie at that point.
17 They knew that Dr. Clayman had lied, and he lied
18 repeatedly. They knew that. They knew he lied.

19 That's the first part of a fraud, a
20 misrepresentation.

21 THE COURT: Where in the complaint is the allegation
22 that Allergan makes that connection, that Allergan goes back
23 and tracks by doctor which -- whether the implants are
24 defective or not?

25 MR. GOWDY: I -- Your Honor, there's -- we -- we

1 don't have to show that Allergan went back and made connection
2 or do any type of analysis.

3 What we've alleged is that Allergan was lied to, that
4 the patient was lied to, and that Allergan knew both facts.
5 They got submitted repeatedly false warranty claims.

6 So the fact -- there's -- this is a distraction,
7 which maybe will work with the jury, but it's not about the
8 plausible basis of their knowledge.

9 They were told a lie. They determined it was a lie
10 and they still paid the claim.

11 And this is how they funneled money to the Claymans
12 to fund the surgeries that were unnecessary.

13 THE COURT: But how do we know that they are -- I
14 don't even think in -- your complaint supports the proposition
15 that they pay the claim after determining that it's a fraud.

16 In fact, I think in -- I can't remember if it's in
17 Angell's or Ms. Hicks, in one of them you specifically allege
18 June the 5th as being the date of the submission of the claim
19 and the payment of the claim -- which I'm not sure makes any
20 sense -- but where are the facts that Allergan is getting a
21 warranty claim, examines it, and only then pays it?

22 MR. GOWDY: Your Honor, as far as -- I'm not trying
23 to look on the specifics with Ms. Hicks. But we're alleging a
24 whole course of conduct where they were repeatedly lied to and
25 they repeatedly determined that these were false claims.

1 And so whether they paid the claim first and then
2 determined it was false in an individual transaction, I don't
3 think matters here, because they knew for years that they were
4 being lied to.

5 And I guess, let me -- I mean, I suppose, Your Honor,
6 in your own individual circumstances, if, you know, just
7 hypothetically, if, you know -- I know my opposing counsel
8 didn't like hypotheticals, but I think they're good for you to
9 ask.

10 If you get asked by your son to give the keys, and
11 you give the keys and he goes out and commits a robbery, you've
12 done nothing wrong. You haven't -- you didn't have any
13 knowledge beforehand.

14 But if you learn by reading his text messages, or
15 however you learn -- it doesn't really matter how -- that on
16 the prior ten nights he's gone out at the same time and
17 committed a robbery, and now you give him the keys, you've
18 substantially assisted and you knew what was happening.
19 There's an inference.

20 Here, we don't have ten times; we have 5,000 times.

21 So whether they, on the individual transaction, made
22 the payment before or after their investigation is irrelevant.
23 The course of conduct and the pattern was obvious that
24 Dr. Clayman was lying.

25 THE COURT: And in the -- in the *Perlman* and the

1 *Lawrence* cases, you have the same thing.

2 You have ample facts telling the bank that the
3 individuals are committing fraudulent activity, but it
4 doesn't -- they -- it doesn't -- and in *Perlman*, if I remember
5 correctly, the bank actually froze -- suspected fraudulent
6 activity and froze the account at one point but then reopened
7 it. And the Eleventh Circuit said that was not enough to show
8 actual knowledge.

9 And was only in the, I think, proposed second amended
10 complaint where they added allegations that two different bank
11 officers actually reached a conclusion that there was fraud and
12 then failed to act on it for a three-month period, and only
13 then was there sufficient allegations to support a finding of
14 actual knowledge.

15 And so what I'm -- what I'm concerned about is where
16 the actual knowledge that Dr. Clayman is committing a fraud
17 comes from as opposed to Allergan just pays all warranty
18 claims.

19 I mean, there's not an allegation anywhere in this
20 complaint that suggests Allergan does anything but pay every
21 single warranty claim they get.

22 MR. GOWDY: Your Honor, I -- I think that the Court
23 is imposing something beyond the plausibility requirement.

24 I'm happy to, you know -- the Court is focused, I
25 see, on the *Perlman* case and the *Lawrence* case. I'd be happy

1 to provide some type of short memo to address those.

2 We did, you know, in the page limits provided,
3 distinguish those cases.

4 I think each of these cases is factually intensive,
5 and I don't understand why we have to allege that it denied
6 other claims.

7 What we've shown is that Allergan itself -- what
8 we've alleged is Allergan itself determined that Dr. Clayman
9 was repeatedly lying to Allergan and that it was having the
10 patient sign this lie.

11 That's knowledge that there is a lie, that there is a
12 misrepresentation. And they knew that the reason that
13 Dr. Clayman was lying was to get money for a surgery. And they
14 paid that money.

15 Whether under other circumstance -- if we get to
16 discovery and it turns out that they have paid every -- which,
17 you know, Your Honor, we're at a position here, at the pleading
18 stage, so I'm not sure -- it's kind of amazing we have this
19 much information as it is, but I'm not sure how we would know
20 what would happen with all of their other claims unrelated to
21 Dr. Clayman.

22 So I believe the Court would be imposing something
23 beyond *Iqbal* and *Twombly* if you ruled that way.

24 THE COURT: So a couple questions on that.

25 These cases actually -- the Allergan cases -- the

1 cases against Clayman and Allergan have been pending in state
2 court since 2016 sometime. And there has been discovery that's
3 been ongoing in those cases.

4 MR. GOWDY: That's correct. And that's why we have
5 more facts probably alleged here than you would in a normal
6 complaint, as opposed to if this had been filed directly in
7 federal court.

8 THE COURT: Right. And -- and Allergan has moved to
9 dismiss twice, arguing that there are insufficient allegations
10 to show actual knowledge.

11 MR. GOWDY: Here in federal court. As far as I know,
12 no state judge has dismissed the claims. But, yes, they have
13 moved twice.

14 And I'd also say, you know, that the discovery that
15 we've learned is that the Claymans -- we've tried to get more
16 information from them, Your Honor. When they were deposed,
17 they pled the Fifth.

18 You know, we provided as much information in a
19 complaint, I think, that is possible and --

20 THE COURT: Mr. Gowdy, I think your co-counsel wants
21 to --

22 (Mr. Gowdy confers with Mr. Shakib.)

23 MR. GOWDY: I haven't appeared in the state case,
24 Your Honor, Mr. Shakib is handling the state cases, just
25 reminded me that the discovery was limited in the state case,

1 waiting for a ruling from this Court on the preemption issue.
2 Is that correct?

3 MR. SHAKIB: Yes.

4 MR. GOWDY: Okay. So there hasn't been open-ended
5 discovery there, but there has been some discovery, including
6 an attempt to depose the Claymans, which -- but didn't get any
7 information because of their pleading the Fifth.

8 So I think the Court is coming up with very, you
9 know, making me think. And when we get ready for summary
10 judgment, we'll have to be prepared for that, but we're here at
11 the pleading stage.

12 The Court is focused with me -- I noticed with my
13 opponent, you focused on the preemption arguments, and I'm
14 happy to go over those. But as far as the state elements, I'd
15 like to point the Court to the -- well, I think I -- and I'd
16 like permission to write more on *Lawrence* and *Perlman*, because
17 we -- because of the brief, but I believe those cases are --
18 first of all, they're not binding and they're distinguishable.
19 We addressed them in our papers.

20 THE COURT: You addressed them and you pointed the
21 Court to *Chang*.

22 MR. GOWDY: Right.

23 THE COURT: But I felt like in *Chang*, you have an
24 individual with the bank that is affirmatively assisting in the
25 conduct.

1 They -- the individual lets them open an escrow
2 account, titled an escrow account, even though it doesn't have
3 the escrow account projections, and writes a false letter
4 overstating the balance in the account. And so the -- there's
5 an individual that's actually participating in the scheme and
6 that was sufficient for actual knowledge.

7 So I don't think we have anything like that here, so
8 I didn't really think that *Chang* was terribly helpful to this
9 analysis.

10 MR. GOWDY: Yeah. I think if you read the *Halberstam*
11 case -- and I know it's from 1983 -- but the reality is, Your
12 Honor, you don't get a lot of cases on substantial assistance
13 or a civil conspiracy.

14 And what we've heard here from the defense is kind of
15 the garden variety products liability defenses, which don't
16 really apply here.

17 But the reality is, is this is a very uncommon case.
18 You don't often have doctors who lie to their patients
19 repeatedly, submit false claims, have those claims paid
20 repeatedly.

21 We put in our chart, you know, millions of dollars
22 getting funneled to them to do unnecessary surgeries while they
23 have this overall business relationship with Allergan where
24 they're a top-10 purchaser of Allergan's products in the state
25 of Florida, where they're Diamond Partners, where we have

1 allegations in the complaint that they -- Dr. Clayman said he
2 knew he'd get away with this because he was a Diamond Partner
3 with Allergan.

4 We have a lot of facts in this case about knowledge,
5 Your Honor, and I think -- and substantial assistance, as well
6 as an implicit agreement.

7 THE COURT: Are you -- are you aware of any case in
8 which an aiding and abetting claim has been upheld in a
9 circumstance like this where you're seeking to hold a business
10 liable for aiding and abetting based on the bad acts of its
11 customer, just because they continued to do business with the
12 customer?

13 MR. GOWDY: I think the closest case -- and I want to
14 go, if you give me just one second, Your Honor, to look at our
15 response.

16 THE COURT: Sure.

17 MR. GOWDY: But we cited it, and I reread it this
18 morning.

19 The *MP, LLC* case, and I also -- which we cite from
20 the Third District Court of Appeal of Florida, as well as the
21 *Cordell Consultant* Case, Your Honor, which is from the
22 Eleventh Circuit and dealt with attorneys.

23 THE COURT: Oh, yeah. But they're -- there, it
24 wasn't simply that they continued to do business. In those --
25 certainly in the *Cordell* case, the attorneys were actively

1 involved in --

2 MR. GOWDY: Right. I agree.

3 I mean, to answer your question of do I have a case
4 exactly like this?

5 No. The Claymans are unique.

6 The extent of this fraud is almost incredulous. And
7 I guess you would say: Well, that makes it implausible.

8 But it's -- the Claymans aren't here. The Claymans
9 have pled the Fifth. The Claymans clearly defrauded these
10 women.

11 THE COURT: The allegation --

12 MR. GOWDY: And so we have to prove -- I'm sorry,
13 Your Honor, I didn't mean to cut you off.

14 THE COURT: That's okay.

15 The allegations in the complaint of the Claymans'
16 conduct, taken as true, are abhorrent. No doubt about it.
17 There's no question about that.

18 MR. GOWDY: Right. So we only have to show
19 accomplice liability here.

20 And, you know, in the *Mink* case -- where I think Your
21 Honor has gotten the preemption argument, so I don't want to
22 belabor it -- there, the physician was making
23 misrepresentations.

24 THE COURT: I'm not terribly persuaded by the
25 preemption argument.

1 MR. GOWDY: Right. But I -- but I want to make this
2 analogy, because it relates to the state law claims, too.

3 THE COURT: Okay.

4 MR. GOWDY: In that in *Mink*, if you just look at the
5 misrepresentation, which was fraud, the company was held -- the
6 manufacturer of the device was held liable under an agency
7 theory, right, for the wrongdoing of the doctor, for the lies
8 told by the doctor.

9 So here, we're not -- we're not alleging agency.

10 THE COURT: Yeah, I was going to say --

11 MR. GOWDY: But it's another form of -- where you're
12 liable for what somebody else did wrong, you know.

13 So Ms. Hamilton may not have murdered somebody, but
14 she was liable in the *Halberstam* case for a murder, which is a
15 the most awful act possible, and which she probably never
16 thought she would be held liable for.

17 Just like if you were to give your -- if you were to
18 give gas money to your teenage son and you had just read texts,
19 knowing that he might be going out and committing a robbery,
20 you're criminally responsible now.

21 It doesn't seem like it's that big of a thing. I
22 just gave gas money to my son. You know, I was just going
23 along with my significant other in the *Halberstam* case.

24 So we don't have to show that Allergan was as evil as
25 the Claymans. We have to show, one, that there was a fraud by

1 the primary wrongdoer, which seems undisputed here.

2 Two, that Allergan knew of that fraud or breach of
3 fiduciary duty.

4 I've gone over, Your Honor, with all -- we don't have
5 to show that they were, you know, sending e-mails, saying:
6 Hey, we're committing fraud. I've gone over, Your Honor, the
7 facts as alleged that show that they knew.

8 THE COURT: Well, okay. They knew -- the warranty
9 department knew when it looked at the -- or, sorry, not the
10 warranty, the lab examined the implant and determined that the
11 implant is not defective.

12 MR. GOWDY: Right.

13 THE COURT: You allege that.

14 MR. GOWDY: That a lie was told. That a lie was
15 told. That's what that means. They knew a lie was told.

16 THE COURT: So every single warranty claim or every
17 single implant that is submitted for warranty that doesn't show
18 a defect means a lie was told?

19 MR. GOWDY: Yes. Especially -- and I guess what I
20 would say is this --

21 THE COURT: It can never be a mistake or --

22 MR. GOWDY: Oh, it could be.

23 THE COURT: -- bad doctor?

24 MR. GOWDY: It absolutely could be. But you're now
25 looking at it in isolation.

1 And this -- you know, they talk about Rule 404 --
2 and, Your Honor, I'm sure, is familiar with similar act
3 evidence.

4 THE COURT: Oh, yes.

5 MR. GOWDY: So if my child falls one time, it may be
6 an accident. If my child falls ten times, they're going to
7 start looking at me. That seems too coincidental.

8 Here, we have 5,000 lies told.

9 THE COURT: But, Mr. Gowdy, where is the allegation
10 that Allergan ever went back and made that determination, that
11 it tracks it?

12 MR. GOWDY: We don't have to allege that they tracked
13 it. What we have to be --

14 THE COURT: But why doesn't that make it like the
15 bank cases?

16 MR. GOWDY: Because, Your Honor, in the bank cases,
17 what the Court held was that there was no duty to investigate.

18 Here, they didn't have to do any investigation. They
19 had 5,000 lies told to them again and again and again, and they
20 kept paying the claims. And -- I don't want this to be missed,
21 Your Honor -- part of analyzing this is motive. Motive is
22 relevant. And we've alleged that.

23 Why -- they make it out like: Well, why would we pay
24 this?

25 Well, because they had a great business relationship

1 with the Claymans. The Claymans were bringing them a ton of
2 money through other sources besides the implants, in addition
3 to the implants.

4 And so they had a motive to know and substantially
5 assist the fraud, and that's -- that is far more than enough to
6 get past plausibility.

7 In the bank cases, Your Honor, I don't know -- I'll
8 dig down to that and would ask that the Court give us leave to
9 write a supplemental memorandum -- I don't think there was that
10 motive. You've got motive here. It was a very profitable
11 relationship.

12 And I don't want the Court to overlook -- and they
13 say it's irrelevant, and I guess we'll have a motion in limine
14 on that -- this is a repeated pattern by this defendant.
15 They've done this same type of -- they've bribed doctors again
16 and again and again.

17 THE COURT: Well, you allege all of the kickback
18 schemes, but this is -- this is different than that.

19 MR. GOWDY: This is different -- well, the reason the
20 kickback statute doesn't apply, those involve when Medicaid is
21 paying. Here, our clients were paying.

22 If Medicaid or Medicare or a federal government was
23 paying, it would fall under the kickback statute.

24 And so here we're under state law making the same
25 type allegations of fraud. They have a -- they're a repeat

1 player in funneling money to physicians. And so it is
2 plausible that they knew and substantially assisted. It is
3 plausible that they had an implicit agreement to do an unlawful
4 act. And they had the overt act, which is repeated payment of
5 money.

6 They funded this scheme by the Claymans. Allergan
7 funded it. Without that money, the Claymans would have been
8 shut down.

9 And none of these women -- or I shouldn't say "none,"
10 but not nearly the number of women would have been harmed as
11 happened here.

12 THE COURT: Address Mr. McGuirl's arguments regarding
13 the absence of any duty on behalf of Allergan to determine
14 whether the providers to whom they sell the implants are
15 committing malpractice or even committing fraud.

16 MR. GOWDY: We agree they don't have a duty. This
17 isn't an omission case. This isn't a negligence case. This is
18 an intentional tort case.

19 I don't have a duty to go into your home, but if I go
20 into your home and I murder you, I'm liable for wrongful death.

21 They don't have a duty to go do investigation. But
22 they did investigate, in fact, and they learned of the fraud,
23 and then they kept funding it.

24 So they had -- they -- their argument is if this is a
25 negligence or a product defect, strict liability claim, you get

1 into whether or not there was a duty to put another warning
2 or --

3 THE COURT: The strict liability negligence claims
4 went away. They were in the first complaint.

5 MR. GOWDY: Yeah. But that's what -- they're arguing
6 like they're still there.

7 This isn't a duty case. This is I did -- there was
8 an intentional tort committed by the Claymans, and they --
9 Allergan substantially assisted in it, with knowledge. They're
10 accomplice liability. Happens in criminal court every day.

11 People are in the car, didn't know everything, but
12 knew enough that they shouldn't have been in the car, and
13 therefore they're liable for what goes wrong inside the
14 convenience store.

15 They knew enough that they're liable for what went
16 wrong at the Claymans' practice.

17 And I think if we were in a criminal court, if we're
18 dealing with conspiracy under Section -- I think it's 841, if I
19 recall correctly.

20 THE COURT: 846.

21 MR. GOWDY: 846. Thank you, Your Honor. I think
22 this case would be going to a jury. I mean, it's -- it's
23 clear.

24 So anyway, I don't know if the Court -- I've tried to
25 answer -- I did have a couple things I wanted to point out to

1 the Court.

2 THE COURT: Go ahead.

3 MR. GOWDY: Just that, you know, in evaluating the
4 substantial assistance, *Halberstam* talks about the duration of
5 the assistance as a critical factor, which we have here, as
6 well as the relation to the other tortfeasor. We have a strong
7 business relationship here. And the amount of the assistance
8 given by the defendant. Allergan funded this fraudulent
9 scheme, Your Honor.

10 THE COURT: Does it -- does it matter, Mr. Gowdy,
11 whether Allergan simply paid all warranty claims?

12 MR. GOWDY: I think it may matter to a jury.

13 And if they bring forth evidence that they paid every
14 single warranty claim for other providers, which we don't have
15 access to, if they bring forward that evidence that for every
16 provider in Florida or the United States or Northeast Florida,
17 they always paid it, does it matter? Yes, it's relevant. It
18 doesn't matter, though, for purposes of plausibility.

19 I mean, I don't know how we would allege that.

20 So I think if you make that a barrier to court, I'm
21 not sure we'll ever be able to overcome it to get that type of
22 information.

23 I think -- I know we're past 11:30, and we've gone
24 over an hour --

25 THE COURT: That's okay.

1 MR. GOWDY: I'm not going to -- I'm not going to take
2 any time, then, on the preemption argument. It sounds like the
3 Court is convinced on that.

4 THE COURT: Well, I'm going to give Mr. McGuirl a
5 rebuttal and let him also respond to some of your -- but go
6 ahead.

7 MR. GOWDY: I just want to look at my notes.

8 It's not a big thing, but Your Honor is correct about
9 you have to decide the validity of the state law claims first.

10 This is a -- it's not just *Mink* that says that, it
11 makes sense from anybody who understands constitutional law.

12 Every time you rule that a state law, whether it be
13 the common law or statute, is preempted, you're making a ruling
14 under the supremacy clause of the Federal Constitution, and
15 your duty is to avoid constitutional issues when possible.

16 And so what -- statement in *Mink*, it's not just some
17 nice thing, it's a long-standing principle that you should
18 avoid constitutional issues, if possible. And therefore you
19 don't just jump right to the preemption. You first determine
20 the scope of the state law, what the state law requires, and
21 you need to examine those questions first.

22 And *Mink* says it, too, pretty black and white. So
23 I'm not sure why they structured their arguments contrary to
24 *Mink*, and, you know, a host of precedent saying that courts
25 should not reach constitutional questions as a threshold

1 matter, but they do.

2 THE COURT: All right. Thank you, Mr. Gowdy.

3 MR. GOWDY: Thanks, Your Honor.

4 THE COURT: Mr. McGuirl, as I said, I guess, to me,
5 this -- the claims rise and fall on whether the plaintiff has
6 adequately pled actual knowledge.

7 Because, in my mind, if they've pled actual
8 knowledge, regardless of where that actual knowledge comes
9 from, then it's not preempted.

10 I understand that it's your contention that if the
11 actual knowledge came from the examination of the device
12 because of the FDA requirements, then that plucks it out and
13 makes it preempted, but I'm not terribly persuaded by that.
14 But I'll certainly hear from you again as to either that or
15 anything that -- and that -- actually, before we do that, why
16 isn't what Mr. Gowdy is saying correct?

17 I mean, why -- if -- they have alleged that Allergan
18 knew that there were 5,000 false representations to the client
19 of leak or rupture, and they paid those 5,000 claims, why isn't
20 that actual knowledge of the misrepresentation to the client --
21 or to the patient? Pardon me.

22 MR. MCGUIRL: He hasn't pled -- the problem is making
23 the connection, as you observed earlier on.

24 They don't make the connection between some data over
25 here -- nobody goes and says: Hey, you know what, let's do an

1 analysis by physician. And let's see what that -- let's sort
2 it out by physician, and now let's go over and let's compare it
3 to claims by physician. And they just -- they simply don't
4 plead that connection. And they don't plead -- and you need
5 actual knowledge.

6 You know, they plead that it could have been done --
7 and one of the -- two of Mr. Gowdy's examples really drive this
8 home.

9 I mean, somebody's teenage son we were talking about.

10 THE COURT: Hopefully not mine.

11 MR. MCGUIRL: But do you remember each one -- at one
12 point when he was arguing this, he said: We don't -- we don't
13 need to show they did an analysis.

14 But each of those examples, you see what he did? He
15 said: Well, if he just was going to take the car and commit a
16 robbery or something, that's not enough.

17 Well, that's what they've pled.

18 But each time he makes the connections: Oh, I'll
19 give you all the text messages, so the connection was made. So
20 he gives the connection.

21 He's actually telling you you do need the connection
22 in all those, and that's what makes the difference.

23 The problem here is the fact that you have data
24 sitting over some place that could be analyzed in some fashion
25 and could possibly be used to make a connection in some other

1 place, he's not pleading that that was done. He's pleading it
2 could have been done.

3 He's pleading looking at it now. We think, now
4 looking at it, that looks pretty fishy to us.

5 THE COURT: What about paragraph 50 that says -- and
6 this is in the Angell complaint: At the time Allergan received
7 the warranty claim made by the Claymans on June 5th, 2015,
8 Allergan had already received from the Claymans at least 4,750
9 warranty claims for saline breast implants that Allergan knew
10 did not demonstrate a loss of shell integrity.

11 And so what they would say is, from that, isn't the
12 plausible inference that they -- because it's a warranty claim,
13 it has -- the warranty only covers ruptures, deflation, and
14 leaks.

15 So if they've got a warranty claim, then that 4,750
16 claims of deflation, rupture, or leak that Allergan has
17 determined did not occur.

18 MR. MCGUIRL: Well, if you put --

19 THE COURT: Is that not an allegation of the
20 connection?

21 MR. MCGUIRL: If he's saying that -- you listen to
22 that, and when you put it together like that, you can say:
23 Well, I guess if you put it all together like that, I can see
24 something there. But he's not alleging that, in fact, they did
25 do that.

1 He's not alleging that the data from the lab tests
2 was brought over and compared to the CP claims. He's just, you
3 know, raising his hands, going: Well, they should have been
4 able to do this somehow, and somehow this could have been done
5 and it would have shown something.

6 By the way, all that -- you know, to get to another
7 point. What Your Honor is saying is all they're doing on these
8 warranty claims, which are contractual, all they're doing is
9 what they agreed to do.

10 THE COURT: Mr. McGuirl, how could they ever allege
11 more than that?

12 I mean, what Mr. Gowdy is saying is that: Okay. By
13 the time you did Ms. Angell's second surgery or you paid her
14 second warranty claim, you had had almost 5,000 warranty claims
15 where you had determined that there was no rupture, leak, or
16 deflation.

17 MR. MCGUIRL: You'd have to say more, Judge.

18 You'd have to say: That's true. And then we took
19 those claims, which are in the abstract, and we took them and
20 we sorted them or we had them sorted by physician.

21 THE COURT: How could any plaintiff ever get that
22 knowledge without discovery?

23 How could they ever state that claim?

24 MR. MCGUIRL: They could allege it. They could
25 allege it, that somehow we did this.

1 They know what we're doing for the FDA. They could
2 have alleged that you put it together, you tracked it to these
3 physicians -- and even if you did track it to those physicians,
4 what does it show?

5 It shows he probably shouldn't been paying those
6 claims, but it doesn't quite tell you what went on between the
7 patient and the physician.

8 In other words, there's some factual truth to that,
9 but it doesn't show that we had actual knowledge that that
10 means more.

11 We actually know that means -- when you read that
12 sentence, we now know everybody is committing malpractice and
13 lying. It doesn't mean that.

14 You could -- you could look at that and wonder if
15 something is askance, but there's no allegation people even did
16 that.

17 THE COURT: Well, you say they could make that
18 allegation. But Rule 11 prohibits them from making an
19 allegation that they don't have facts to support.

20 So how -- I mean, aren't you creating a pleading
21 impossibility for the plaintiffs?

22 What more can they say other than after 5,000,
23 shouldn't somebody or isn't it obvious that somebody knew?

24 MR. MCGUIRL: Wouldn't it be that they were tracked
25 to these physicians, and then correlated back to the CP claims,

1 and that's where the comparison was done between the two?

2 THE COURT: I'm sorry, CP claim?

3 MR. MCGUIRL: The warranty claim.

4 Because if you don't do that -- if you don't do that,
5 it shows nothing. It shows nothing.

6 You have a lot of -- you have a lot of lab tests that
7 are not being sorted by doctors. You just do the lab test and
8 send it off, data.

9 Who knows where it comes from?

10 THE COURT: Well, that's not in the complaint,
11 whether it's sorted by doctors or not.

12 MR. MCGUIRL: Exactly, it's not. That's right, it's
13 not in the complaint. It's missing.

14 THE COURT: But isn't the -- based on paragraph 50 --

15 MR. MCGUIRL: It's a conclusion that they knew. It's
16 a conclusion. It's a conclusion that they did the analysis.
17 But it doesn't allege what the -- it doesn't tell you that they
18 did this analysis.

19 It's just: Here's the results. Skip what needed to
20 be done to get there. Let's not deal with that.

21 They don't allege that the data was sorted by doctor.
22 They don't allege that they then took that data and compared it
23 to the warranty claims and that's how they learned this.

24 They don't allege that because that's not what
25 they're alleging.

1 Mr. Gowdy just said it. We don't need to show there
2 was an analysis. We just need to show sort of a generalized
3 awareness that they could have seen this if they wanted to.

4 Well, that's what Your Honor was talking about. The
5 idea that you could have is not the same as actual knowledge,
6 that you actually did and make the connection.

7 Could they have done it? Yes, I guess we all know
8 now they could have done it.

9 Did they do it? Was there actual knowledge?

10 He doesn't plead that. He actually said: I don't
11 need to have an analysis.

12 THE COURT: Is Allergan still selling implants -- is
13 it still a Diamond Partner with Dr. Clayman?

14 MR. MCGUIRL: I don't really know the answer to that,
15 but I'm guessing -- I don't know, Judge. I really don't know.

16 MR. SHAKIB: Yes, Your Honor, they are.

17 MR. MCGUIRL: Oh, okay.

18 I refer the last thing, Judge, the ZP case by Judge
19 Franco, actually talks about the need for actual knowledge.

20 And it goes to the state claims. Because both of the
21 state claims really need actual knowledge. Conspiracy and
22 aiding and abetting, they need actual knowledge to survive.

23 Thank you, Judge.

24 THE COURT: Thank you.

25 Mr. Gowdy, anything else you want to address, sir?

1 MR. GOWDY: Well, I just would like the permission of
2 the Court -- or another minute.

3 The *Perlman* and *Lawrence* case, I'd be happy to submit
4 three page, four page, just on those, if it would help the
5 Court.

6 I'm looking here and I noticed that while the Court
7 found that the first amended complaint didn't state a claim, it
8 directed that the second amended complaint that was submitted
9 did.

10 THE COURT: In *Perlman*?

11 MR. GOWDY: Yes.

12 THE COURT: And in *Perlman*, the difference between
13 the first amended complaint and the proposed second amended
14 complaint was that in *Perlman*, in the proposed second amended
15 complaint, there were two -- there was an investigator and a
16 bank officer who actually looked -- there were allegations that
17 they actually looked into the transactions and drew the
18 inference, made the conclusion that there was a fraud.

19 One determined that the account should be shut down,
20 but didn't shut it down for three months; the other determined
21 that the actions should be reported to law enforcement, but
22 didn't do anything for three months.

23 And it was those additional allegations of -- of the
24 bank officers or the bank employees drawing the inference and
25 making the conclusion that nudged the complaints over the

1 plausibility standard in the second *Perlman*, at least that was
2 my reading of it.

3 MR. GOWDY: Right. So Your Honor is very well
4 prepared, perhaps more than me on these two cases, I'm
5 embarrassed to say, and I just -- if these cause you any
6 concern, I'd like the opportunity to address them briefly in
7 writing.

8 THE COURT: Sure. Let me give you a deadline.

9 MR. GOWDY: Thank you, Your Honor.

10 THE COURT: Today is what? Today is June 20th.

11 Do you think you could -- I'd like to work on this
12 while it's fresh in my brain.

13 MR. GOWDY: I could do it by whenever Your Honor
14 wants it. Just tell us. We'll get it done.

15 THE COURT: Do you think you could get it to me by
16 Monday?

17 MR. GOWDY: Yes, Your Honor.

18 THE COURT: I mean, is that -- is that an
19 unreasonable request?

20 Well, how about Tuesday?

21 MR. GOWDY: I'll always take more time.

22 THE COURT: And Mr. McGuirl is going to stand up and
23 say he wants to respond.

24 And so, Mr. McGuirl, by the following Friday.

25 MR. MCGUIRL: Thank you, Judge.

1 THE COURT: So Mr. Gowdy, by the 25th, please. And
2 I'll just, in fairness, let's say by 5:00 p.m. on the 25th.

3 And then, Mr. McGuirl, if you'll give me your
4 response by the 28th so that I can have this matter fully
5 briefed.

6 MR. MCGUIRL: Thank you, Judge.

7 MR. GOWDY: And do you want to impose -- I would, if
8 I were you, impose a page limit?

9 THE COURT: Yeah, no more than five pages.

10 I'm more generous than what you requested.

11 MR. GOWDY: Thank you, Your Honor.

12 MR. MCGUIRL: Thank you, Judge.

13 THE COURT: All right. And just so counsel are
14 aware, the courtroom is filled with the law students, future
15 lawyers of the future -- future lawyers of the future. Wow,
16 that was bad. So future lawyers, so you have just given them
17 an excellent example of well-prepared lawyers who know their
18 subject matter and practice appropriately before the Court, and
19 so I thank you for doing that.

20 All right. We're in recess.

21 COURT SECURITY OFFICER: All rise.

22 (Proceedings concluded at 11:53 a.m.)

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C E R T I F I C A T E

UNITED STATES DISTRICT COURT)

MIDDLE DISTRICT OF FLORIDA)

I hereby certify that the foregoing transcript is a true
and correct computer-aided transcription of my stenotype notes
taken at the time and place indicated herein.

Dated this 24th day of June 2019.

/s/Cindy Packevicz Jarriel

Cindy Packevicz Jarriel, RPR, FCRR